PATENT
Attorney Docket No.: 020460-000210US
Client Ref. No.: 111-1-CIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No. 1955
SIRHAN, MOTASIM et al.	Examiner: THALER, MICHAEL H.
Application No.: 09/872,640	Technology Center/Art Unit: 3731
Filed: May 31, 2001	
For: CATHETER HAVING EXCHANGEABLE BALLOON	**DECLARATION**
Customer No.: 20350	**UNDER 37 C.F.R. § 1.132**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Udayan Patel, declare as follows:

1. I graduated from Bombay University in 1979 with a Bachelor of Science degree in Chemistry and Physics. After obtaining my degree at Bombay University, I attended the University of Lowell where I received a Master of Science in Polymer Science in 1985 and a Master of Science in Engineering Plastics in 1990. I have over fifteen years of product development experience, particularly in the medical device field. From 1991 to 2001, I worked

as a Senior Engineer and later as Program Manager of Product Development for Guidant Corporation evaluating, designing, developing, and manufacturing angioplasty catheters, percutaneous transluminal coronary angioplasty catheters, and other balloon catheters. From 2001 to 2002, I served as Director of Research and Development for Advanced Stent Technologies, Inc. managing development and manufacture of vascular stents. Since 2002 to the present, I have been at Avantec Vascular Corporation, the assignee of U.S. Patent Application No. 09/872,640 ("the '640 application"). At Avantec Vascular Corporation I have been managing development of percutaneous transluminal angioplasty balloon catheters and percutaneous transluminal coronary angioplasty balloon catheters. A copy of my *Curricular Vitae* is attached hereto as Appendix A.

2. I have read and understand the specification, drawings, and claims of the '640 application.

3. The following is a copy of claim 1 in the '640 application:

> *1. An intravascular balloon catheter comprising:*
>
> *a catheter body having a proximal end, a distal end, a guidewire lumen, and an axially slit passage along at least a portion thereof; and*
>
> *a first balloon structure comprising a balloon and a passage slidably receivable over the catheter body and an inflation tube removably receivable in the axially slit passage.*

4. I have reviewed the Examiner's Office Action dated October 5, 2004. I understand that the Examiner's position is that:

> [t]he claims(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which is it is most nearly connected, to make and/or use

> the invention. The embodiment of figures 5A, 5B and 13A, as described in the specification and shown in the drawings, is inoperable. The distal end of the inflation tube 26 is shown attached to the back end of inner sleeve 38 in figure 2. Although the inflation tube 26 is slidable within slit 24 since it has a cross-section which is smaller than the cross-section of slit 24, the inner sleeve 38 (which is located relative to the inflation tube 26 as shown in figure 2) will not fit into slit 24. Since the wall of the inner sleeve 38 is located directly in line with the inflation tube 26 as shown in figure 2, the balloon structure 14 is not slidable relative to the catheter body 12 shown in figure 5A, 5B and 13A.

Office Action, page 3. For the reasons given below, I disagree with the Examiner's position. Specifically, one of skill in the art at the time the application was filed, May of 2001, could have made the claimed balloon catheter of claim 1 based upon the specification and drawings of the '640 application coupled with information known in the art without undue or unreasonable experimentation.

5. Firstly, independent claim 1 is directed at an intravascular balloon catheter as shown in the alternative constructions of Figs. 5A and 13A of the '640 application. As described on page 10, line 27 through page 13, line 20 and page 14, lines 21-30 of the '640 application, Figs. 5A and 13A show a cross sectional profile of the alternative embodiment at a midpoint of a catheter body at lines 5-5 of Fig. 2 and at lines 13-13 of Fig. 12, respectively. Specifically, as shown in Figs. 2, 4, 5A, and 13A of the '640 application, the intravascular balloon catheter (10) comprises the catheter body (12) and a first balloon structure (14). The catheter body (12) has a proximal end (16), a distal end (18), a guidewire lumen (20), and an axially slit passage (24) along at least a portion thereof. The first balloon structure (14) comprises a balloon (40), a passage (41) slidably receivable over the catheter body (12), and an inflation tube (26) removably receivable in the axially slit passage (24). Those of skill in the art in May of 2001 could have constructed the claimed balloon catheter of claim 1 based on this patent application disclosure without any undue or unreasonable experimentation.

6. Secondly, with respect to Examiner's position as noted above in paragraph 4, those of skill in the art would recognize that claim 1 requires that the passage (41) of the balloon structure (14) is slidably receivable over the catheter body (12) and that the inflation tube (26) of the balloon structure (14) is removably receivable in the axially slit passage (24) of the catheter body (12) as clearly described on page 12, lines 3-19 of the '640 application. Further, those of skill in the art would further recognize that Claim 1 clearly does not require that the inner sleeve (38) be removably received within the axial slit (24) of the catheter body (12), as suggested by the Examiner.

7. I further understand that the Examiner's position is that:

> [i]f the inner sleeve 38 is located on the outer surface of the catheter body 12, it is unclear what tube or other member connects the inflation tube 26 to the balloon. If there is such a tube, it appears that it must be smaller in diameter than the width of the narrow portion of slit 24 shown at the outer periphery of catheter body 12 shown in figure 13A (since it must pass radially outward from inflation tube 26 to the balloon through this portion of slit 24). Yet, no tube or its dimensions are disclosed.

Office Action, pages 3-4. Those of skill in the art in May of 2001 could have constructed the connection between the inflation tube (26) and the balloon (40) in a number of several ways without undue or unreasonable experimentation, particularly in light of the predictability associated with the mechanical arts.

8. One simple example that could have been easily constructed by one of skill in the art in May of 2001 based upon the mid-section illustrations of Figs. 5A and 13A from the '640 application of this claimed embodiment without undue or unreasonable experimentation is shown in Appendix B, attached hereto. In this example, the intravascular balloon catheter (10) comprises a catheter body (12) and a first balloon structure (14). The catheter body (12) has a distal end (18), a guidewire lumen (20), and an axially slit passage (24) along at least a portion thereof. The first balloon structure (14) comprises a balloon (40), an inner sleeve (38) slidably receivable over the catheter

body (12), and an inflation tube (26) removably receivable in the axially slit passage (24). A cross sectional view at a midpoint of the balloon catheter (10) taken along lines 13A-13A is illustrated in Fig. 13A in the '640 application. A distal cross sectional view taken along lines A-A is similar to Fig. 13A, but now shows the sleeve (38) of the balloon structure (14) slidably receivable over the catheter body (12) and the inflation tube (26) of the balloon structure (14) removably receivable in the axially slit passage (24) of the catheter body (12) as clearly described on page 12, lines 3-19 of the '640 application.

9. In this example, the next distal cross sectional view taken along lines B-B illustrates that a distal end of the inflation tube (26) forms an S shape tube that has a smaller diameter than a width of the narrow portion of the slit (24) so as extend out of the axial slit (24) and so as to connect to and communicate with the balloon structure (40) as described on page 12, lines 20-23. I disagree with the Examiner's position that "it is not clear from the original disclosure that the tube 26 would be sufficiently flexible to make an abrupt bend out of slit 24 and make another bend to connect to the balloon 40." Office Action, page 4. One of skill in the art in the medical device field would recognize that the S shaped inflation tube (26) having a smaller diameter than a width of the narrow portion of the slit (24) may be formed from a variety of flexible and non-flexible materials. From my fifteen years of experience in researching and developing catheters and balloon catheters, a variety of conventional tubing materials may be employed to form a S shaped tube, such as polymers or metals. In this example, the balloon (40) at a proximal end is attached to the inflation tube (26) and the inner sleeve (38) as shown in view B-B and at a distal end to the inner sleeve (38) as shown in view C-C so as to allow the balloon to be pressurized.

10. For the reasons given above, one of skill in the art in May of 2001 could have made the claimed balloon catheter of claim 1 based upon the specification and drawings of the '640 application coupled with information known in the art without undue or unreasonable experimentation.

11. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of Unites States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 5/16/05

Udayan Patel

Attachments
60435523 v1

CURRICULUM VITAE

Udayan Patel
6508 Deer Hollow Drive, San Jose, CA 95120
408-202-7691

Summary Of Qualification

Senior level manager with 15 years Product Development experience and have received 10 patents. Leader with demonstrated record of successful product commercialization of medical devices.

Champion at organizing and leading winning teams to develop and bring forth revolutionary products into medical device market. Demonstrated technical leadership skills in research, product development, and manufacturing.

Professional Experience

Avantec Vascular Corporation, CA; Div. of Goodman & Co., Japan
(2/02-Present)

Technical Fellow, R&D
Responsible for development of PTA and PTCA products. Currently responsible for development of drug eluting stents. One patent application pending.

Advanced Stent Technologies, Inc, CA (4/01 – 1/02)

Director, R&D
Responsible for development and ramp-up into manufacturing of new products. Developed product through IDE filing and approval. Two patent applications pending approval.

Guidant Corporation, Santa Clara, CA. (10/91 – 3/01)

Program Manager, Product Development
3/'97 – 3/'01
Responsible for design, development, and ramp-up into manufacturing of novel PTA balloon catheters and stents. Organized and coached three product teams through multiple generations of products.

CURRICULUM VITAE

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Manager, Materials Technology
9/'95 – 2/'97
Responsible for assembling a materials technology group consisting of senior level engineers to develop new materials for various components of the balloon catheter.
Supported Legal Department in creating Patenting strategy and organize portfolio of intellectual properties for the technology group. Initiated weekly forums for sharing new technology progress with the rest of the organization. Established technology project priorities with corporate re-engineering team.

Senior Engineer II
1/'95-8/'95
Responsible for establishing "Technology Skunkworks" group consisting of core group of engineers to seek new technologies that would seed new product ideas or lower the cost of manufacturing. Three patents were generated. One product idea was implemented in the field of adhesives.

12/'93-12/'94.
Worked with heavyweight cross-functional team for development of PTCA catheter. Supervised a group of engineers and technicians in designing tooling for extrusions, selection of materials, and optimization of secondary processes. Conducted the development and manufacturing of a new balloon material for PTCA catheters and achieved highest yields (98%). Introduced new catheter shaft materials and multi-lumen extrusions.

Senior Engineer I
10/'91-11/'93.
Responsible for evaluating new materials for angioplasty catheters.

Inland Fisher Guide, General Motors Corp., Troy, MI. 1/90 – 10/91

Senior Manufacturing Engineer
Responsible for developing new materials and processes for exterior body panels.
* Eliminated streaking of metallic particles during extrusion.
* Developed segmented screw for versatility in single screw extrusion process.
* Other projects: New co-extrusion die design for manufacturing fiber-glass composite body side molding (BSM); develop mold and screen materials for door panels using processes such as co-injection molding and gas-assist injection molding; injection molding of front fender and quarter glass window encapsulation; studied benefits and limitations of hybrid molding processes such

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as extrusion-compression molding and three dimensional co-extrusion blow molding.

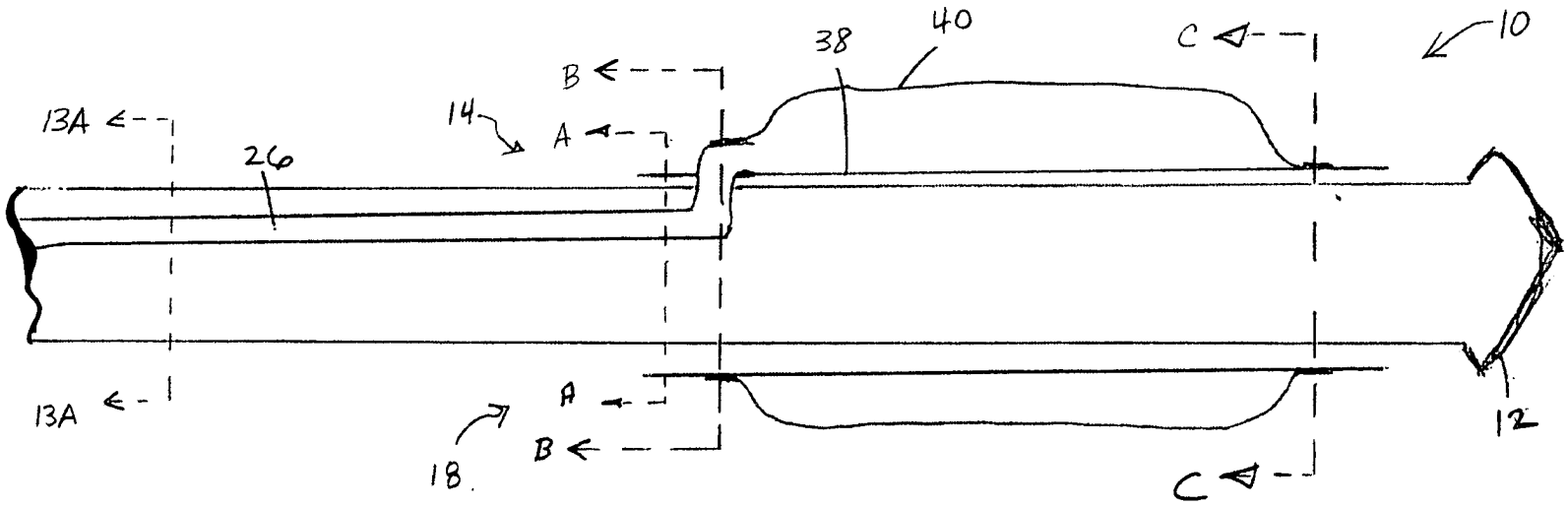
EDUCATION

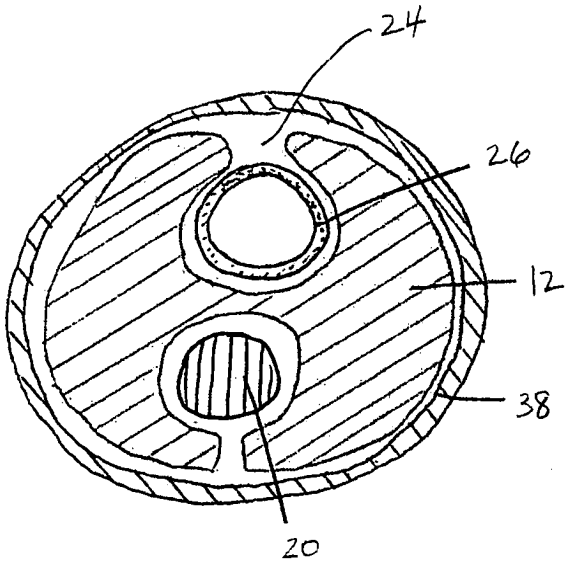
1998 MBA, University of Phoenix, San Jose Campus.

1990 MS in Engineering, Plastics, University of Lowell, Lowell, MA.

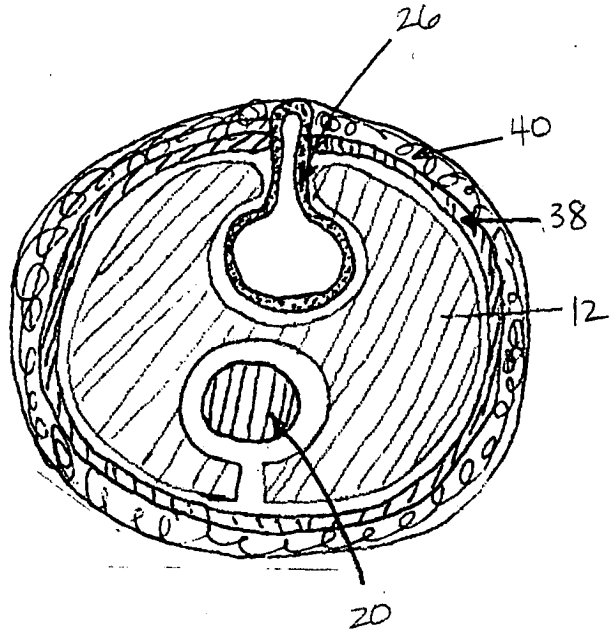
1985 MS, Polymer Science, University of Lowell, Lowell, MA.

1979 BS, Chemistry/Physics. Bombay University, Bombay, India.

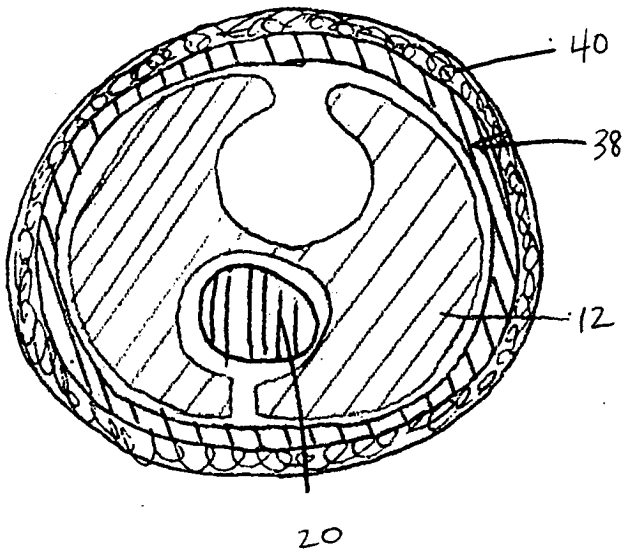




A-A



B-B



C-C

APPENDIX B